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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,364	05/09/2005	Yoshinori Hishikawa	029650-170	4895
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EXAMINER KOHARSKI, CHRISTOPHER				
ART UNIT 3763		PAPER NUMBER		
NOTIFICATION DATE 09/09/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/534,364

Applicant(s)

HISHIKAWA ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 3-11 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CDC)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 05/28/2009 in which claims 4 and 5 were amended and new claim 11 was added. Currently claims 1 and 3-11 are pending for examination in this application. Additionally, the Examiner also acknowledges the amendments to the disclosure, specifically the abstract. Further in response to Applicant's claim of foreign priority, the Office Action Summary now reflects this submission, as well as the filed DEO acceptance mailed 09/07/2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

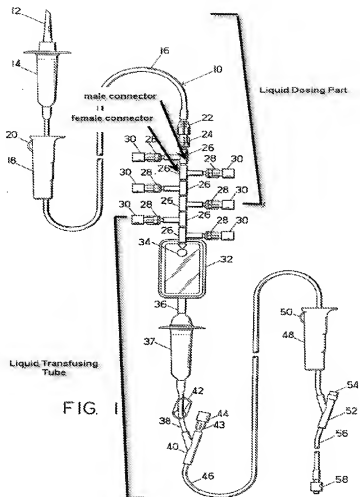
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gula et al. (USPN4,447,230). Gula et al. discloses an intravenous administration set assembly.

Regarding claims 1 and 5-11, Gula et al. discloses a liquid transfusing assembly (Figure 1) comprising: a tube constituting a liquid transfusing channel (fluid channel from element 16-26-46); a connector (26) provided at one end part of said tube and directly connected thereto; and a connection part (opposite side of element 26) provided on the other side of said tube and connected to the side of a containing part containing a transfusion (connected to spike 12); wherein said connector includes a male

connector and a female connector (tee spike distal/proximal ends (26)), and the axis of said male connector and the axis of said female connector substantially coincide with each other (along longitudinal axis of center of tee spikes 26); and a liquid dosing part (assembly from 12-upper tee connector 26) for dosing a patient with said transfusion, said liquid dosing part having a liquid dosing part side connector (upper tee 26) capable of being connected to one of said male connector and said female connector of said connector of said liquid transfusing tube (46-26); wherein in the condition where one of said male connector and said female connector of said connector of said liquid transfusing tube and said liquid dosing part side connector of said liquid dosing part are connected with each other, the other of said male connector and said female connector of said connector of said liquid transfusing tube can be connected to a liquid transfusing tube other than said liquid transfusing tube (Figure 1, see marked up figure below).

Gula et al. further discloses the liquid dosing part having a bacteria-removing filter (32, col 3, ln 55-65) provided on the downstream side relative to said liquid dosing part side connector; wherein said liquid dosing part has a mixing injection port (43) on the downstream side (defined as fluid flow from 12 to 58) of said bacteria-removing filter (32); and wherein said liquid dosing part side connector is branched into a plurality of parts (tees 26) so that a connector provided on the other end side of a tube having on its one end side a connection part connected to another liquid container (tee ends 28) other than said liquid container and said connector of said liquid transfusing tube can be simultaneously connected (Figure 1, col 3, ln 30-55, see marked up figure below).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-4 are rejected under 35 U.S.C 103(a) as being unpatentable over Gula et al. (USPN4,447,230) in view of Boyle et al. (USPN4,734,091). Gula et al. meets the claim limitations as described above except for the channel changeover function and inner cavity fluid communication.

However, Boyle et al. teaches a filtered manifold apparatus and method of ophthalmic irrigation.

Regarding claims 3-4, Boyle et al. teaches a liquid transfusing assembly (Figure 1) with a liquid transfusing tube (60) connected to a plurality of 3-way stopcock valves (54) connected to a transfusion source (12) with each valve configured to change fluid channels via the valve stem (110) to fluidly connect the male/female ends (Figure 3, col 4, ln 10-45).

At the time of the invention, it would have been obvious to incorporate the 3-way valve stems of Boyle et al. to the system of Gula et al. in order to allow for fluid control through the infusion tube assembly and allow for fluid channel closing when valve is not in use. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have

combined the teachings in the references in light of the disclosure of Boyle et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 05/28/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Gula et al. (USPN4,447,230) does not disclose "a connector including a male connector and a female connector and provided at one end part of the tube constituting a liquid transfusing channel" and "that the other of the male connector and the female connector of the connector of the liquid transfusing tube is exposed as an open connection port to receive a male or female connector of the another liquid transfusing tube."

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the Gula et al. (USPN4,447,230) reference discloses the claimed invention. Regarding the Gula et al. reference, the Examiner asserts that Gula et al. discloses connector (26) including a male connector and a female connector (portions of tee fitting, each includes male and female portions) and provided at one end part of the tube (assembly 16-26-46, the connector is present at the distal end on the assembly)) constituting a liquid transfusing channel" and "that the other of the male connector and the female connector (each tee fitting, sections near (24, 34, and 30) of the connector of the liquid transfusing tube is exposed as an open connection port

(each are open as connection points to other assembly items) to receive a male or female connector of the another liquid transfusing tube.”

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

The Examiner suggests clarification of the claims to include specific structure of the connection assembly and specific arrangement of the liquid transfusion assembly elements.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/31/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763